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New Stark Rules Raise Compliance Challenges

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The Centers for Medicare & Medicaid Services ("CMS") issued a final rule on July 31, 2008 that makes important changes to the physician self-referral law (the "Stark" law). As health care providers know, Stark imposes complex restrictions on the financial relationships between referring physicians and entities that provide designated health services (a "DHS entity"). Many of these relationships will now need to be restructured in order to comply with Stark. Highlights of major changes from the final rule issued on July 31, 2008 are as follows:

Services Provided "Under Arrangements"

After the final rule takes effect in October 2009, most referring physicians will no longer be allowed to own interests in entities that provide services "under arrangements" with hospitals. Physician-owned entities or physician-hospital joint ventures often contract to provide services to hospitals "under arrangements," meaning that the physician-owned entity or joint venture provides services under a contract with the hospital, and the hospital then bills for those services. In the past, these arrangements were permitted under Stark because the definition of a DHS entity was limited to the entity billing for the services. The final rule revises the definition of a DHS entity to include physician-owned entities that perform services under arrangements. Under the new definition, both the entity that bills for DHS (the hospital) and the entity that performs DHS (the physician-owned entity) will be treated as furnishing DHS. This means that in order to comply with Stark, the financial relationship between the entity that performs DHS and its physician owners must meet a Stark exception, which would not be possible in most cases.

Percentage-Based Lease Arrangements

In the past, CMS has expressed concern over the use of percentage-based compensation outside the context of physician services that are personally performed. Space and equipment leases often use a percentage-based formula to determine rental charges. In this latest rule change, CMS has done away with percentage-based compensation for the rental of office space and equipment. The final rule prohibits the use of compensation formulae based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the leased office space or through the use of the leased equipment. Space and equipment leases that rely on a percentage-based formula to determine rental charges will need to be restructured before the October 2009 effective date. CMS notes that it intends to monitor percentage-based arrangements for other non-professional services, such as management and billing, and we may see similar limitations on these arrangements in the future.

Per-Click Lease Arrangements

The final rule also restricts the use of rental charges based on units of service ("per-click" charges). CMS has stated that per-click lease arrangements are inherently suspect because the physician lessor is paid per unit of service and thus has a greater incentive to refer patients to the entity leasing

the space or equipment. The final rule prohibits per-click rental charges to the extent they reflect services provided to patients referred between the lessor and the lessee. CMS clarifies that the restriction on per-click charges applies regardless of whether the lessor is a physician, an entity in which the physician has an ownership or investment interest, or a DHS entity that refers patients to a physician lessee.

Stand in the Shoes

In response to industry concerns, CMS makes welcome revisions to the physician "stand in the shoes" rule. At present, a physician is deemed to stand in the shoes of his or her physician organization, meaning that any financial relationship between the physician organization and a DHS entity must satisfy a Stark direct exception. Under the new rule, only those physicians with an ownership or investment interest in a physician organization will be deemed to stand in the shoes of the physician organization.

Amendments to Agreements

CMS has also reversed its prior position on amending agreements for space and equipment leases and personal service arrangements. These agreements may now be amended without violating the requirement that compensation be "set in advance," as long as certain criteria are met. This means that parties will not need to adhere to the formality of executing new agreements for the same space, equipment, or services.

Period of Disallowance

The final rule also clarifies the "period of disallowance" during which a physician cannot refer and an entity cannot bill for DHS because their financial relationship does not meet a Stark exception. The period of disallowance runs from the time when the relationship first fails to meet a Stark exception until all the requirements of a Stark exception are satisfied.

Alternative Method for Compliance

CMS has adopted an alternative method for compliance when an entity has not yet collected all the required signatures for an agreement. As long as all the other requirements of the applicable Stark exception are met, and the signatures are obtained within 30 or 90 days after the financial relationship has begun, the entity may still receive payment for DHS.

More Changes Ahead

CMS is now working to finalize the 2009 Medicare Physician Fee Schedule, which will also likely contain rule changes that will impact the application of the Stark law. Current indications are that any additional rule changes will be published in early November. As a result, it is important for health care providers and their counsel to keep an eye on additional developments while working to make changes to existing arrangements as necessary to ensure compliance with the rule changes that have already been finalized.

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